

**IN THE CLAIMS:**

1. (Original) A pharmaceutical kit for nasal drug delivery comprising:  
an aqueous solution of cyanocobalamin and excipients in a container and;  
a droplet-generating actuator attached to said container and fluidly connected to the cyanocobalamin solution in the container; wherein said actuator produces a spray of the cyanocobalamin solution through a tip of the actuator when said actuator is engaged, wherein said spray of cyanocobalamin solution has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.
2. (Original) The kit of claim 1 wherein said spray comprises droplets wherein less than 5% of said droplets are less than 10  $\mu\text{m}$  in size.
3. (Currently Amended) The kit of claim 1 wherein ~~in~~ the aqueous solution of cyanocobalamin has a viscosity of less than 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin of about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that mercury and mercury containing compounds are not present in the solution.
4. (Original) The kit of claim 3 wherein the spray is comprised of droplets of the cyanocobalamin solution wherein less than 5% of the droplets are less than 10  $\mu\text{m}$  in size.
5. (Original) The kit of claim 3 wherein the spray has a spray pattern major axis and minor axis of between 25 and 40 mm each.
6. (Original) The kit of claim 3 wherein the solution of cyanocobalamin is further comprised of citric acid and sodium citrate wherein the solution has a pH of from about 4-6.
7. (Original) The kit of claim 6 wherein the pH of the solution is about 5.
8. (Original) The kit of claim 3 wherein cyanocobalamin is present in solution at a concentration of between 0.5-1 % by weight.

9. (Original) The kit of claim 8 wherein the concentration of cyanocobalamin in solution is about- 0.5%.

10. (Original) The kit of claim 6 wherein the citric acid is present in solution at a concentration of about 0.12%, and the sodium citrate is present in solution at a concentration of about 0.32%, in water.

11. (Original) The kit of claim 3 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution wherein 50% of the droplets are 26.9  $\mu\text{m}$  or less in size.

12. (Original) The kit of claim 3 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution, wherein 90% of the droplets are 55.3  $\mu\text{m}$  or less in size.

13. (Currently Amended) The ~~product~~ kit of claim 3 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5  $\mu\text{m}$  or less in size.

14. (Original) A kit for administering intranasally a cyanocobalamin solution comprised of a container, a solution of cyanocobalamin in the container, and an actuator attached to said container, wherein a spray of cyanocobalamin solution is expelled through a tip of said actuator when said actuator is engaged wherein said aqueous solution of cyanocobalamin

is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when

administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the solution of cyanocobalamin contains no mercury or mercury-containing compounds, and wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.

15. (Original) The kit of claim 14 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution, wherein less than 5 % of the droplets of the cyanocobalamin spray are less than 10  $\mu\text{m}$  in size.

16. (Currently Amended) The kit of claim ~~12~~ 14 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution, and wherein 50% of the droplets of the cyanocobalamin spray are 26.9  $\mu\text{m}$  or less in size.

~~15~~ 17. (Currently Amended/Renumbered) The ~~method~~ kit of claim ~~12~~ 14 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3  $\mu\text{m}$  or less in size.

~~16~~ 18. (Currently Amended/Renumbered) The ~~method~~ kit of claim ~~12~~ 14 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5  $\mu\text{m}$  or less in size.

~~17~~ 19. (Currently Amended/Renumbered) The ~~method~~ kit of claim ~~12~~ 14 wherein the spray has a spray pattern major axis of about 35.3 mm and a minor axis of about 30.8 mm.

~~18~~ 20. (Currently Amended/Renumbered) A method for administering cyanocobalamin intranasally comprised of providing an aqueous solution of cyanocobalamin, wherein the solution of cyanocobalamin has a viscosity of less than 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin of about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that mercury and mercury containing compounds are not present in the solution, wherein the cyanocobalamin formulation is administered into a nose of an individual through an

actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.

~~19~~ 21. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein the spray produces droplets, wherein less than 5% of the droplets are less than 10  $\mu\text{m}$  in size.

~~20~~ 22. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein the spray has a spray pattern major axis and minor axis of between 25 and 40 mm each.

~~21~~ 23. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein the solution of cyanocobalamin is further comprised of citric acid and sodium citrate wherein the solution has a pH of from about 4-6.

~~22~~ 24. (Currently Amended/Renumbered) The method of claim ~~21~~ 23 wherein the pH of the solution is about 5.

~~23~~ 25. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein cyanocobalamin is present in solution at a concentration of between 0.5-1 % by weight.

~~24~~ 26. (Currently Amended/Renumbered) The method of claim ~~6~~ 20 wherein the concentration of cyanocobalamin in solution is about 0.5%.

~~25~~ 27. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein the citric acid is present in solution at a concentration of about 0.12%, and the sodium citrate is present in solution at a concentration of about 0.32%, in water.

~~26~~ 28. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 50% of the droplets are 26.9  $\mu\text{m}$  or less in size.

~~27~~ 29. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3  $\mu\text{m}$  or less in size.

~~28~~ 30. (Currently Amended/Renumbered) The method of claim ~~18~~ 20 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5  $\mu\text{m}$  or less in size.

~~29~~ 31. (Currently Amended/Renumbered) A method for administering cyanocobalamin comprised of providing an aqueous solution of cyanocobalamin wherein said aqueous solution of cyanocobalamin is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the solution of cyanocobalamin contains no mercury or mercury-containing compounds, and wherein the cyanocobalamin solution is administered into a nose of an individual through an actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.

~~30~~ 32. (Currently Amended/Renumbered) The method of claim ~~29~~ 31 wherein the cyanocobalamin spray produces droplets of the solution, wherein less than 5 % of the droplets are less than 10  $\mu\text{m}$  in size.

~~31~~ 33. (Currently Amended/Renumbered) The method of claim ~~29~~ 31 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 50% of the droplets are 26.9  $\mu\text{m}$  or less in size.

~~32~~ 34. (Currently Amended/Renumbered) The method of claim ~~29~~ 31 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3  $\mu\text{m}$  or less in size.

~~33~~ 35. (Currently Amended/Renumbered) The method of claim ~~29~~ 31 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5  $\mu\text{m}$  or less in size.

~~34~~ 36. (Currently Amended/Renumbered) The method of claim ~~29~~ 31 wherein the spray has a spray pattern major axis and a minor axis of about 25 - 40 mm each.

~~35~~ 37. (Currently Amended/Renumbered) A method for elevating the vitamin B12 levels in the cerebral spinal fluid (CSF) comprising administering intranasally a sufficient amount of a solution of cyanocobalamin so that the average ratio of vitamin B 12 in the CSF to that in the blood serum ( $E12\text{ CSF}/B12\text{ Serum} \times 100$ ) is increased to at least about 1.1, wherein said aqueous solution of cyanocobalamin is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the cyanocobalamin solution contains no mercury or mercury-containing compounds and wherein the cyanocobalamin solution is administered into a nose of an individual through an actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.

~~36~~ 38. (Currently Amended/Renumbered) The method of claim ~~35~~ 37 wherein the cyanocobalamin spray produces droplets of the solution, wherein less than 5 % of the droplets are less than 10  $\mu\text{m}$  in size.

~~37~~ 39. (Currently Amended/Renumbered) The method of claim ~~35~~ 37 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 50% of the droplets are 26.9  $\mu\text{m}$  or less in size.

~~38~~ 40. (Currently Amended/Renumbered) The method of claim ~~35~~ 37 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3  $\mu\text{m}$  or less in size.

~~39~~ 41. (Currently Amended/Renumbered) The method of claim ~~35~~ 37 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5  $\mu\text{m}$  or less in size.

40 42. (Currently Amended/Renumbered) The method of claim ~~35~~ 37 wherein the spray has a spray pattern major axis and a minor axis of between 25 - 40 mm each.